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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,147	12/07/2001	Frank Blecha	23625-DIV1	7389
7590	03/28/2005		EXAMINER	
Tracey S. Truitt Suite 400 2405 Grand Boulevard Kansas City, MO 64108			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/014,147

Applicant(s)

BLECHA ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 4-8 is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Pursuant to the directives of the response filed 12/14/04, claims 1 and 2 have been amended, claim 3 cancelled, and claims 12-17 added. Claims 1, 2, 4-8, 12-17 are now pending.

Applicants' arguments filed 12/14/04 have been considered and found persuasive. The previously imposed rejections are withdrawn.



Newly submitted claim 2 is directed to an invention that is independent or distinct from the invention originally claimed.

The originally claimed invention was drawn to a method of using compounds which consist of amino acids only. Claim 2, by contrast, is drawn to a method of using polynucleotides.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 2 is withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.



The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 recites that the peptide has between 15 and 39 amino acids, and at the same time, has at least 15 contiguous amino acids of the peptide of SEQ ID NO: 1.

However, there does not appear to be descriptive support for this. Applicants are requested to point to the page and line number(s) where support can be found.



Claims 12-17 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 12 is drawn to a method of attracting a leukocyte to a wound location, or to an area of inflammation. According to what is asserted by the claim, any leukocyte can be attracted to any location, irrespective of the route of administration, or the anatomical site of administration. The phrase "attracting leukocytes to a [specific] location" implies that there will be more leukocytes at the target site than at all other sites.

However, it is far from clear how this might be achieved. For example, if the spinal cord is inflamed, would the peptide migrate specifically to the spinal cord merely as a result of intravenous administration of the peptide? Or suppose that there is a fungal infection on a person's foot, resulting in inflamed tissue at that location. Would intracerebral administration of the peptide cause the peptide to migrate specifically to the foot? Or suppose that a person's eye is inflamed. Would intradermal administration of the peptide via a "patch" on the person's back cause the peptide to migrate to the eye?

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

There is no evidence that the peptide, once administered, will demonstrate any preference for tissues that are inflamed or wounded. There are no "working examples" which show this, and no evidence from the prior art to support such an assertion.

Another issue concerns the term "organism". Is it really the case that injection of the peptide into an echinoderm, hermit crab, fruit fly or oak tree will influence the movement of

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leukocytes?

Accordingly, "undue experimentation" would be required to practice the claimed invention.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

*D. Lukton*  
DAVID LUKTON  
PATENT EXAMINER  
GROUP 1200